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## **PITFALLS IN DETERMINING THE PROPHYLACTIC OR CURATIVE VALUE OF BACTERIAL VACCINES.**

### **WITH SPECIAL REFERENCE TO INFLUENZA.**

By G. W. McCoy, Director, Hygienic Laboratory, United States Public Health Service.

During the prevalence of the epidemic of influenza and pneumonia from which the country is just emerging, the writer had an opportunity to examine data on the value of certain bacterial vaccines designed for prophylactic or curative use against the infection.

The inadequacy of the evidence adduced to support the claims of certain preparations has been very striking. This paper is presented in order that the kinds of data on which conclusions may properly be based may be generally understood.

Perhaps the commonest source of error is that due to the employment of a vaccine in an institution, or in a group not in an institution, after cases of the disease have appeared. Influenza develops among the persons in a given group, prophylactic vaccinations are undertaken more or less promptly, and no cases may occur after the inoculations have been completed. The results appear most impressive when the number of cases among vaccinated and unvaccinated is presented; but when closer examination reveals the fact that so large a proportion of the personnel involved has developed the disease before the vaccinations were done, that in all probability the remainder would not sicken, whether vaccinated or not, the figures lose their significance. An example will, perhaps, make this clearer. It was reported that among a large group of hospital attendants, approximately one-third had been vaccinated and all had remained free from the disease, while the remaining two-thirds of the persons had not been vaccinated, all of whom had developed influenza. This appeared to be a very striking example of the prophylactic value of the vaccine, but when the fact was brought out that the vaccinations were only begun after practically all of the two-thirds mentioned had become ill, the significance attributed to these figures was nullified, while the conviction remained that only the naturally immune had been vaccinated, it being unusual for more than two-thirds of the personnel in any group to develop influenza.

Somewhat similar were the data presented to support a claim for the efficiency of a vaccine which had been used in a large group of persons in a civil community. It was shown that but 2 per cent of those who had been vaccinated developed the disease; while in the community at large the incidence had been about 5 per cent. The figures looked significant until it was learned that the vaccinations had not been completed until the community had suffered from the epidemic for several weeks, and that about half of the 5 per cent of

cases had occurred before the vaccinations were completed. Omitting these, there remained so few cases in the large unvaccinated group as compared with those that had occurred among the vaccinated, that the difference was not striking enough to be regarded as satisfactory evidence.

A second source of error occurs in vaccinating all persons in a group, large or small, and interpreting failure of the disease to appear or to spread as evidence of protection. One has but to study the data with regard to certain institutions, where, without vaccinations, the disease has been excluded or has spread but slightly, to realize how fallacious are such arguments. Thus, the writer is acquainted with a large group, where vaccinations have been done and where a rigid quarantine has been in force, which has remained free from the disease; and he is acquainted with a number of institutions where the same result has been obtained by quarantine alone.

The third, and perhaps commonest, pitfall is the drawing of conclusions from too meager data. Thus, one observer assured me that he had been exposed to influenza patients many times and had taken no precautions beyond being vaccinated and he had not developed the disease. Evidence of this sort should be given no consideration, as many of us, the majority, indeed, have escaped the disease without having taken any particular means to prevent it.

We hear of numerous examples of the cure of cases by means of vaccine. I have heard related the most astonishing examples of apparent great benefit from vaccines in the pneumonia that follows influenza. When the records were scrutinized, however, it was found that these remarkable cases could be duplicated by others that had done equally well without vaccine.

In the only examples with which I am familiar in which a vaccine was used on alternate cases, no better results were secured in the vaccinated than in the control group.

The writer suspects that those who have used vaccines most commonly have been more facile in making the diagnosis of a complicating pneumonia than have others. The author has examined numerous clinical records submitted to support the value of vaccines in pneumonia, and many of the cases, judged by the evidence presented, most certainly would not ordinarily have been regarded as pneumonia. Physical signs were equivocal or could probably be attributed to bronchial involvement when there was no definite acceleration of respiration, and the general trend of the record did not support the view that the patient had pneumonia. In a certain large hospital, on one service, about 60 per cent of the cases admitted were diagnosed pneumonia and all were treated with vaccine, with a mortality of about 10 per cent, while in the same institution, on

another service, about 15 per cent of cases were diagnosed pneumonia and the mortality was 40 per cent. In this instance, the actual number of deaths was approximately the same, but vaccine-treated cases showed a much lower case-mortality in the pneumonias. I am by no means sure that the higher percentage of pneumonias diagnosed may not have been more nearly accurate than the lower, but it should not be made the basis of misleading deductions.

The only way in which we are to secure promptly acceptable evidence of the value of a bacterial vaccine is by the vaccination of only a portion of the individuals in a large group, holding the remainder as controls; age, sex, and conditions of exposure being the same in the two groups.

On the other hand, a vaccine should not be condemned unless controlled as just indicated, and unless it has failed to show protective value when sufficient time has elapsed after the inoculation to make it reasonably likely that any immunity which may develop will have had an opportunity to do so.

A large number of vaccines have been used, some made from the influenza bacillus alone, others from this in conjunction with pneumococci, staphylococci, and streptococci, and in various combinations; the failure of one does not necessarily mean the uselessness of others.

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## NARCOTIC DRUGS—INTERPRETATION OF HARRISON ACT.

### THE UNITED STATES SUPREME COURT HOLDS THAT SECTION 2 IS CONSTITUTIONAL.

Two opinions relative to the so-called Harrison Narcotic Drug Act have recently been rendered by the United States Supreme Court. Both cases arose under section 2 of the act, the constitutionality of this section being brought into question.

In the first case<sup>1</sup> the defendant, a physician, was indicted for selling and distributing narcotic drugs unlawfully because not in pursuance of a written order on a form furnished for the purpose, and for selling and distributing narcotic drugs not in the course of professional practice. The United States District Court for the western district of Texas held that section 2 was unconstitutional because it was not a revenue measure but an invasion of the police power reserved to the States. This decision the Supreme Court reversed, holding the act to be within the taxing authority of Congress.

In the second case<sup>2</sup> the defendants were convicted and sentenced in the United States District Court for the western district of Tennessee on a charge of conspiracy to violate the Harrison Act. The facts were that one of the defendants, a physician, prescribed morphine for habitual users without intent to effect a cure but to keep

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<sup>1</sup> *United States v. Doremus*, 39 Sup. Ct., 214.

<sup>2</sup> *Webb et al. v. United States*, 39 Sup. Ct., 217.